

EXHIBIT 8

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Inspections, Compliance, Enforcement, and Criminal Investigations

Capitol Foods, Inc. 5/17/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Baltimore District Office
Central Region
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Baltimore, MD 21215
Telephone: (410) 779-5455
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FEI: 3007242585

WARNING LETTER CMS# 295679

May 17, 2012

Certified Mail Return Receipt Requested

Mr. Scott Yun, President
Capitol Foods, Inc.
1320 5th Street NE
Washington, DC 20002

Dear Mr. Yun:

We inspected your firm, a multiple food warehouse and ready-to-eat (RTE) shrimp egg roll manufacturer, located at 1320 5th Street NE, Washington, DC on March 19, 20, 21, and 27, 2012. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your fish and fishery products are adulterated, as they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the current edition of the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov¹.

Additionally, our review of the labeling for your Shrimp Egg Roll product revealed that this product is also adulterated within the meaning of 402(c) and misbranded within the meaning of Section 403 of the Act [21 U.S.C. §343] and the regulations for food labeling at Title 21, Code of Federal Regulations, Part 101 (21 CFR 101).

Specifically, our inspection of your facility revealed the following seafood HACCP violations:

- 1.) You must conduct, or have conducted for you, a hazard analysis for each kind of fish and fishery product you process to determine whether there are food safety hazards which are reasonably likely to occur, and you must have and implement a written HACCP plan to control any food safety hazard which are reasonably likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for your RTE shrimp egg rolls to control the food safety hazards of pathogen growth and toxin formation from time/temperature abuse and (undeclared allergenic

substances. Additionally, we suggest you refer to the tables in Chapter 3 of the 4th Edition of FDA's Fish and Fishery Products Hazards and Controls Guidance (i.e., the Hazards Guide) to assess when conducting your hazard analysis, whether there are additional hazards associated with your products, your process and/or your packaging. Once you have identified any additional hazards, the Hazards Guide then provides references to the appropriate chapters which in turn provide information and assistance in selecting adequate controls for your products and processes.

2.) You must maintain sanitation control records that, at a minimum, document monitoring and corrections set out in 21 CFR 123.11(b), to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for safety of water, condition and cleanliness of food contact surfaces, prevention of cross-contamination from insanitary objects, maintenance of hand washing, hand sanitizing, and toilet facilities, protection of food, food packaging material, and food contact surfaces from adulteration, proper labeling, storage and use of toxic chemicals, control of employee health conditions, and exclusion of pests. Specifically, you do not have any sanitation monitoring records for your RTE shrimp egg rolls.

Labeling:

1.) Your Shrimp Egg Roll product is adulterated within the meaning of section 402(c) of the Act [21 U.S.C. § 342(c)] because the product bears or contains a color additive which is unsafe within the meaning of section 721(a) of the Act [21 U.S.C. § 379(a)]. Section 721(a) deems a color additive to be unsafe unless its use is in conformity with the color additive's listing regulation. Specifically, the listing regulation for FD&C Yellow No. 5 requires that the color additive be listed by that name in the ingredient list on the labels of foods for human use [CFR 74.705(d)(2)]. Your Shrimp Egg Roll product is manufactured with **(b)(4)** which contains FD&C Yellow #5; however, the label for the finished products fails to declare the presence of FD&C Yellow #5 in the ingredient statements.

2.) Your Shrimp Egg Roll product is misbranded within the meaning of section 403(k) of the Act [21 U.S.C. § 343(k)] because it contains an artificial flavoring, coloring, or chemical preservative. In accordance with 21 CFR 101.22(k), the label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients. Your product is manufactured with **(b)(4)** which contains certified color additive FD&C Yellow #5 and FD&C Yellow #6; however, your finished product label fails to identify the presence of these color additives. Under 21 CFR 101.22(k)(1), certified colors must be declared by the name of the color additive listed in the applicable regulation in part 74 or part 82 of this chapter. The common or usual name may be abbreviated to omit the "FD&C" prefix and the term "No." (e.g., Yellow 5).

3.) Your Shrimp Egg Roll product is misbranded within the meaning of section 403(w) of the Act, [21 U.S.C. § 343(w)] in that the product fails to declare completely or accurately the known major food allergen, wheat as specified by the Act.

Section 201(qq) of the Act [21 U.S.C. § 321(qq)] defines as "major food allergens" milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as any food ingredient that contains protein derived from one of these foods, with the exception of highly refined oils.

A food is misbranded if it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either:

- the word "Contains," followed by the name of the food source from which the major food allergen is derived, is printed immediately after or adjacent to the list of ingredients, section 403(w)(1)(A) of the Act, 21 U.S.C. § 343(w)(1)(A); or
- the common or usual name of the major food allergen in the list of ingredients is followed in parentheses by the name of the food source from which the major food allergen is derived, e.g. "(wheat)," except that the name of the food source is not required when either the common or usual name of the ingredient uses the name of the food source or the name of the food source appears elsewhere in the ingredient list (unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of an ingredient that is not a major food allergen), section 403(w)(1)(B) of the Act, 21 U.S.C. § 343(w)(1)(B).

Further guidance and information on food allergens can be accessed on FDA's website at

<http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm>²

4.) Your Shrimp Egg Roll product is misbranded within the meaning of Section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] because it is fabricated from two or more ingredients, and the label fails to

declare the common or usual name of each ingredient as required by 21 CFR 101.4(b). For example

- You fail to declare the **(b)(4)** ingredient as well as its sub-ingredients used to manufacture your product.
- The statement "fried in vegetable oil" is not provided for in 21 CFR 101.4." Fat and/or oil ingredients must be declared in accordance with 21 CFR 101.4(b)(14).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We also note the following comments about your products labels:

- Your product label only provides a numeric count. As required by 21 CFR 101.1 05(c), when the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information. Count is not sufficient because the weight can vary. The net quantity of contents must include the net weight.
- Your product label contains information in two languages. In accordance with 21 CFR 101.15(c)(2), if a product label contains any representation in a foreign language or foreign characters, all words, statements, and other information required by or under authority of the Act to appear on the label must appear in the foreign language.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR 123) and the Current Good Manufacturing Practice regulation (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Ernest F. Bizjak, Compliance Officer at the address above. If you have questions regarding any issues in this letter, please contact Mr. Bizjak at 410-779-5715.

Sincerely yours,

/S/

Evelyn Bonnin
District Director
Baltimore District Office

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1. <http://www.fda.gov/>
2. <http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm>